



USDA Foreign Agricultural Service

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## Japan

### Sanitary/Phytosanitary/Food Safety

### Foreign Laboratory Approval Program for Japan

## 2004

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**Report Highlights:**

The Japanese Ministry of Health, Labor and Welfare (MHLW) approves foreign laboratories for performing chemical analysis of food and food-related to be exported to Japan. Under the program, food and food-related products imported into Japan are exempted from certain analytical tests such as those for pesticide residues, food additives and packaging materials if valid test results are certified by an MHLW-approved laboratory in exporting countries.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Tokyo [JA1]  
[JA]

## **Outline of the Foreign Laboratory Approval Program by the Japanese Ministry of Health, Labor and Welfare (MHLW)**

The program developed by the Japanese Ministry of Health, Labor and Welfare (MHLW) to approve foreign laboratories for chemical analysis of food and food-related products such as additives and container/packages to be exported to Japan was introduced in March 1982.

Under the program food and food-related products imported into Japan are exempted from certain analytical tests, such as for pesticide residues, food additives and container/package materials, if valid test results are certified by an MHLW-approved laboratory in exporting countries. A heavy emphasis is placed on food additive and pesticide residue analyses. Less emphasis is given to food component analysis during import inspection in Japan. In addition, microbial analyses done by foreign laboratories are not accepted by MHLW. In principle, test results certified by MHLW-approved laboratories for food products are valid for one year.

In order to effectively utilize this program, a foreign laboratory must be determined by MHLW to be eligible to test, among other things, food additives and pesticide residues. To ensure the laboratory's capability for chemical analysis, applicants must provide MHLW with a copy of a certification issued by a State or Federal Government agency accrediting that the laboratory has this capability

### **Procedure to become an MHLW-approved foreign laboratory**

In order to become an approved laboratory of the Japanese Ministry of Health, Labor and Welfare, the laboratory must be capable of conducting analysis in accordance with the AOAC method. Also, it is required that the laboratory be accredited by U.S. federal agencies, such as the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), or the Alcohol and Tobacco Tax and Trade Bureau (TTB). Accreditation from State Government agency programs can also be accepted.

If the laboratory interested in such registration specializes in wine and/or spirits and it is certified by the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Treasury Department, the laboratory should contact TTB's International Trade Division at (202) 927-8110.

If the activities of the laboratory are not related to TTB, the lab may send this office (Agricultural Affairs Office of the U.S. Embassy, Tokyo) their application letter addressed to MHLW with information generally describing its operations including: facilities, number of staff, major line of business, years of operation, etc. In addition, a copy of a certificate issued by appropriate federal or state authorities verifying the laboratory's competency in analytical chemistry is required. The application should be addressed to the following office:

Office of Quarantine Station Administration  
Department of Food Safety  
Pharmaceutical and Food Safety Bureau  
Ministry of Health, Labor & Welfare

The Agricultural Affairs Office of the U.S. Embassy, Tokyo (1-10-5 Akasaka, Minato-ku, Tokyo 107-8420, Japan) will forward this material to MHLW through the Ministry of Foreign Affairs under "Note Verbale" for its approval. When the laboratory becomes approved, we will notify the company applying and forward a revised list of MHLW-certified foreign

laboratories in the United States (showing that the name of the laboratory has been added to the list) when available.

**List of approved laboratories**

A list of approved laboratories in the U.S. is available in the MHLW website (<http://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf>). The list is both in English and Japanese, however, you may need to download the Asian Language Package to read the file.